K042177
p. 1/2

AUG 27 2004

510(k) Summary of Safety and Effectiveness

Date: August 6, 2004

Submitter: GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person: Lisa M. Baumhardt
Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
Phone: 262-293-1699
Fax: 262-293-1460

Device: Trade Name: MAC 5000 ECG Analysis System

Common/Usual Name: Electrocardiograph

Classification Names:

21 CFR 870.1025	Monitor, Physiological Patient (with Arrhythmia Detection or Alarms)	74MHX
21 CFR 870.1025	Detector and Alarm, Arrhythmia	74DSI
21 CFR 870.1425	Programmable Diagnostic Computer	74DQK
21 CFR 870.2340	Electrocardiograph	74FYW
21 CFR 870.2920	Transmitters and Receivers, Electrocardiograph, Telephone	74DXH

Predicate Device: K033492 MAC 5000 ECG Analysis System

Device Description: The MAC 5000 ECG Analysis System is designed to acquire, analyze, display, and record ECG signals from surface ECG electrodes. The device consists of two basic components: the processing unit and the patient acquisition module. Models provide rechargeable battery operation and/or optional trolley for transporting the equipment.

The MAC 5000 can deliver 3, 6, 12, or 15 lead ECG's, 12 lead interpretive analysis, vector loops, and can be upgraded to provide software analysis options such as high resolution signal averaging of QRS and P wave portions of the electrocardiogram. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

The MAC 5000 system acquires ECG data using a modular patient data acquisition device called the CAM14 (K991735). By placing the data acquisition device closer to the patient, signal fidelity is improved and noise is reduced. MAC 5000 delivers 12 or 15 lead ECG's on full-size reports with alphanumeric keyboard for patient demographics and other data entry, a full size VGA graphics and waveform display, integrated thermal writer and removable data storage.

Additionally, the MAC 5000 utilizes battery power for customer convenience and can transmit and receive ECGs to and from a central ECG cardiovascular information system via optional communication links. The system is intended as a mobile device but the main unit can be separated from the trolley and used as a desktop unit.

K042177
p 2/2

Intended Use: The MAC 5000 ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information adult and pediatric populations. Basic systems deliver 3, 6, 12, or 15 lead ECG's, 12 lead interpretive analysis, vector loops, and can be upgraded to provide software analysis options such as high resolution signal averaging of QRS and P wave portions of the electrocardiogram. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

The MAC 5000 is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility.

Technology: The MAC 5000 ECG Analysis System employs the same functional technology as the predicate devices.

Test Summary: The MAC 5000 ECG Analysis System complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Technical Reviews
- Design Reviews
- Code Inspections
- Unit level Testing (module verification)
- Integration Testing (system verification)
- Final Acceptance Testing (validation)
- Performance Testing
- Safety Testing

Conclusion: The results of these measurements demonstrated that the MAC 5000 ECG Analysis System is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2008

GE Medical Systems Information Technologies
c/o Ms. Margaret Mucha
Regulatory Affairs Leader
9900 Innovation Drive
Wauwatosa, WI 53226

Re: K042177
Trade/Device Name: MAC 5500 Resting ECG
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: DPS
Dated: August 6, 2004
Received: August 11, 2004

Dear Ms. Mucha:

This letter corrects our substantially equivalent letter of August 27, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K042177

Device Name: MAC 5000 ECG Analysis System

Indications For Use:

The MAC 5000 ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information adult and pediatric populations. Basic systems deliver 3, 6, 12, or 15 lead ECG's, 12 lead interpretive analysis, vector loops, and can be upgraded to provide software analysis options such as high resolution signal averaging of QRS and P wave portions of the electrocardiogram. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

The MAC 5000 is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility.

Prescription Use_X_
(Per 21 CFR 801.109 Subpart D)

OR

Over-The-Counter Use____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042177